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EXAMINER	
ARIANI, KADE	

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/555,244	MILLER, WINFRIED	
	Examiner	Art Unit	
	Kade Ariani	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25,28-33 and 35-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25,28-33 and 35-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on December 4, 2009 has been received and entered.

New claim 41 is added.

Claims 1-25, 28-33, and 35-41 are pending in this application and were examined on their merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "active ingredients of a food supplement" in claim 24 (line 2) and "the food supplement results in said food product" (line 9) of claim 24 are confusing and therefore indefinite, because it is not clear what is it that the applicants is trying to encompass by these recitations. e.g. product and process of use? or the intended result?

Claim 41 is rejected because it depend on claim 24.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Greenberg (US Patent No. 5, 569,458).

Claim 24 is drawn to a food product comprising following active ingredients, one or more plant protease and/or one or more animal protease, antioxidants comprising vitamins having antioxidant activity, and selenium-containing substances, one or more flavonoids and/or one or more flavonoid-containing substances, and optionally one or more amino acids, one or more polysaccharides, or combinations thereof, wherein the food supplement results to contribute to a balanced diet, strengthens the immune defenses.

Greenberg discloses a dietary supplement comprising bromelain, papain, trypsin, and chymotrypsin (plant and animal proteases), vitamins (A, C and E), selenium-containing substances (selenium amino acid complex), citrus bioflavonoid complex, amino acids (L-glycine), and mucopolysaccharides (polysaccharides) (column 2 lines 64, column 3 lines 1-30 and 33-46). Greenberg further disclose the composition has the ability to strengthen the immune system (column 5 lines 26-28).

Greenberg therefore clearly anticipate the claimed composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-23, 25, 28-33 and 35-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg (US Patent No. 5, 569,458) in view of Shahid et al. (J Assoc Physicians India, 2002, Vol. 50, p.527-531) and further in view of Rayman, M. P. (The Lancet, 2000, Vol. 356, p. 233-241) and Vetvicka et al. (JANA, 2002, Vol. 5, No.2, p.5-9) and Ochao et al. (Journal of Parenteral & Enteral Nutrition, 2001, Vol. 25, No. 1, p.23-29) and Birt et al. (Pharmacology & Therapeutics, 2001, Vol. 90, p.157-177) and Jensen et al. (J. Nutr., 1999, Vol. 129, p.1355-1360), and Hughes et al. (The Journal of infectious diseases, 2000, Vol. 182, Suppl. 1, S11-S15).

Claims 1-23, 25, 28-33 and 35-40 are drawn to a composition comprising one or more plant protease and/or animal protease, wherein said one or more plant protease and/or animal protease have a total concentration of 20% to 60% by weight of active constituents in the composition, antioxidants comprising vitamins having antioxidant activity, and selenium-containing substance, one or more flavonoids and/or one or more flavonoid-containing substances, wherein one or more flavonoid-containing substances have a total concentration of 10% to 50% by weight of active constituents in the

composition, and optionally one or more amino acids, one or more polysaccharides or combinations thereof, one or more amino acids, one or more polysaccharides, one or more polyphenols, plant proteases is/are bromelain, and papain, animal proteases is/are trypsin or chymotrypsin, vitamins are selected from vitamin A, C and E or the esters of vitamin A, and E, flavonoids comprise rutin, flavonoid-containing substances is citrus flavonoids, the composition further comprises coenzyme Q-10, the composition further comprises carotenoids, carotenoids are carotene, amino acid is glycine, wherein the selenium-containing substance having antioxidant activity is sodium selenite present in a concentration of 0.01 to 0.1% by weight, a medicament that strengthens the immune response, a dietetic treatment comprising administering to a patient in need for such treatment the composition of claim 1, said administration strengthens the immune response, method to regulate the immune system and to treat inflammatory disorders.

Greenberg teaches a composition (a dietary supplement, a nutritional formulation) comprising bromelain (minimum 2500 m.c.u) (column 4 line 57), papain, trypsin, and chymotrypsin (plant and animal proteases), vitamins (A, C and E), vitamin E succinate, 69.2 microgram selenium amino acid complex or chelates (selenium-containing substances), proanthocyanidins (also known as OPC, grape seed flavonoid, are polyphenol and a flavonol), citrus bioflavonoid complex, rutin (a polyphenol and a flavonoid), amino acids including L-glycine, polysaccharides (mucopolysaccharides), coenzyme Q-10, β-carotene (carotenoid) (column 2 lines 64, column 3 lines 1-30 and 33-46). Greenberg further teaches the composition strengthens the immune system (column 5 lines 26-28). Greenberg teaches the formulation contain 34.6 mg citrus

bioflavonoid (column 2 lines 58-59, column 3 -continued Table line 14). Greenberg also teaches a method comprising administering the dietary supplement to a patient (one capsule 3 times daily for adults) (column 3 lines 49-50). Moreover, since the specific activity of the enzymes are taught by Greenberg et al., a person of ordinary skill in the art at the time the invention was made, knowing the specific activities of the enzymes, would have been capable of calculating the amount of enzyme (in %) to be added to the formulation based on the total weight according to the teachings of Greenberg et al.

Greenberg does not teach one or more protease have a total concentration of 20% to 60% by weight of active constituents in the composition, and flavonoids have a total concentration of 10% to 50% by weight of active constituents, carotenoid is lycopene, vitamin E acetate, amino acid is L-arginine, polysaccharide is β-glucan, quercetin from onion powder, the selenium-containing substance is sodium selenite in a concentration of 0.01 to 0.1% by weight. However, Shahid et al. teach an oral enzyme formulation comprising, 90 mg bromelain (plant protease), 48 mg trypsin (animal protease), and 100 mg rutin (flavonoid/antioxidant) (Abstract). Shahid et al. teach the oral administration of the proteolytic enzymes formulation regulates the immune function (down-regulates and degrades the over-expressed, inflammation adhesion molecules, promoting its faster clearance) and reduce the intensity of the inflammation (p. 528 1st column 1st paragraph and p.530 1st column 2nd paragraph lines 1-5). The total concentration of the enzymes in the formulation taught by Shahid et al. is 57.9% and rutin is % 42.1 (100- 57.9 = 42.1). Calculated, using the total weight of the ingredients in the formulation, which is equal to 238 mg (90 mg +48 mg + 100 mg = 238 mg), and the

total amount of the enzymes which is 138 mg (bromelain + trypsin or 90 mg + 48 mg = 138 mg).

Rayman teaches immunoenhancing effects of selenium supplementation using 200 µg sodium selenite per day, and that the cells of the immune system need selenium (p.234 1st column 2nd to 4th paragraphs). Rayman teaches because of the variation between individuals in the extent of the response to supplementation the requirements will differ between individuals in the same population (p.239 1st column 1st paragraph). Rayman teaches in sensitive individuals the maximum dietary intake may be as low as 600 µg per day, and it would be prudent to restrict adult intake from all sources to an upper limit of 400 to 450 µg/day as recommended by several expert panels (p.240 1st column 2nd paragraph lines 8-12). Therefore, a person of ordinary skill in the art at the time the invention was made would have known that the amount of sodium selenite to be added to a dietary composition would have depended on the individual's needs, diet, and could have been calculated (in % by wt) according to the recommended dose using the teachings of Rayman.

Vetvicka et al. teach β-glucans, exhibit immunostimulating properties (including antibacterial and anti-tumor activities). Vetvicka et al. teach the results provide preclinical evidence for the beneficial effects of orally-administered β-glucans (Abstract, Introduction p.5, 1st column lines 1-2 and 2nd column 1st paragraph).

Ochao et al. teach dietary L-arginine enhance and stimulate cellular immune response (Abstract, p.24, 1st column 2nd paragraph).

Further motivation to use flavonoid quercetin from onion (non citrus source) is in Birt et al. who teach flavonoids have many biological properties including the ability to regulate and enhance host immune function (p.171 2nd column 3rd paragraph). Birt et al. further teach studies shows that adsorption of quercetin to be 3 fold greater (50% of ingested dose) after ingestion of quercetin predominantly in the glycosodic form from onions (p.165 2nd column 2nd paragraph lines 6-10). It must be noted that quercetin is also found in citrus fruits.

Hughes et al. teach dietary carotenoids (lycopene) enhance immune function (Abstract).

Jensen et al. who teach vitamin E acetate is a better vitamin E source because of higher efficiency of absorption (see Abstract).

Therefore, a person of ordinary skill in the art at the time the invention was made, knowing that oral administration of the proteolytic enzymes formulation (at a total concentration of 20% to 60% by weight) regulates the immune function, would have been motivated to optimize the amount of enzymes and flavonoids in the food composition as taught by Greenberg according to teachings of Shahid et al. with a reasonable expectation of success in order to provide a composition with an improved immune strengthening properties, because Shahid et al. teach oral administration of a proteolytic enzymes formulation (bromelain, trypsin, and rutin, containing 57.9% total enzyme concentration and % 42.1 total flavonoid concentration) regulates the immune function. Moreover, a person of ordinary skill in the art at the time the invention was made, would have been motivated to modify the composition of Greenberg, by using

sodium selenite, β-glucans, L-arginine, flavonoid quercetin from onion, and lycopene according to the teachings of Rayman, Vetvicka et al., Ochao et al., Brit et al., and Hughes et al. with a reasonable expectation of success, in providing a composition with improved immune strengthening properties, because Rayman teaches immunoenhancing effects of sodium selenite, Vetvicka et al. teach β-glucans exhibit immunostimulating properties, Ochao et al. teach dietary L-arginine enhance and stimulate cellular immune response, Brit et al. teach flavonoids have the ability to regulate and enhance host immune function, and because Hughes et al. teach dietary carotenoids (lycopene) enhance immune function. Accordingly, a person of ordinary skill in the art at the time the invention was made, knowing the higher efficiency of absorption of vitamin E acetate, would have been motivated to substitute vitamin E succinate in the Greenberg composition with vitamin E acetate as taught by Jensen et al. with the predictable results of increasing the efficiency of vitamin E absorption. Because substitution of one known element for another would have yielded predictable results to a person of ordinary skill in the art.

Applicant is directed to pages 12-13 of KSR v Teleflex (500 US ___ 2007) " …the Court has held that a "patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men." Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp., 340 U. S. 147, 152 (1950). This is a principal reason for declining to allow patents for what is obvious. The

combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results".

Claims 24 and 41 are rejected are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg (US Patent No. 5, 569,458) in view of Shahid et al. (J Assoc Physicians India, 2002, Vol. 50, p.527-531).

Claims 24 and 41 are drawn to a composition comprising following active ingredients of a food supplement, one or more plant protease and/or one or more animal protease, antioxidants comprising vitamins having antioxidant activity, and selenium-containing substances, one or more flavonoids and/or one or more flavonoid-containing substances, and optionally one or more amino acids, one or more polysaccharides, or combinations thereof, wherein the food supplement results in said food product to contribute to a balanced diet, strengthens the immune defenses, and wherein total concentration of said one or more plant protease is from 20% to 60% by weight of active ingredients.

As mentioned immediately above, Greenberg teaches the limitations of claim 24.

Greenberg does not teach total concentration of said one or more plant protease is from 20% to 60% by weight of active ingredients. However, Shahid et al. teach an oral enzyme formulation comprising, 90 mg bromelain (plant protease), 48 mg trypsin (animal protease), and 100 mg rutin (flavonoid/antioxidant) (Abstract). Shahid et al. teach the oral administration of the proteolytic enzymes formulation regulates the immune function (down-regulates and degrades the over-expressed, inflammation

adhesion molecules, promoting its faster clearance) and reduce the intensity of the inflammation (p. 528 1st column 1st paragraph and p.530 1st column 2nd paragraph lines 1-5). The total concentration of the enzymes in the formulation taught by Shahid et al. is 57.9% and rutin is % 42.1 (100- 57.9 = 42.1). Calculated, using the total weight of the ingredients in the formulation, which is equal to 238 mg (90 mg +48 mg + 100 mg = 238 mg), and the total amount of the enzymes which is 138 mg (bromelain + trypsin or 90 mg + 48 mg = 138 mg).

Therefore, a person of ordinary skill in the art at the time the invention was made, knowing that oral administration of the proteolytic enzymes formulation (at a total concentration of 20% to 60% by weight) regulates the immune function, would have been motivated to optimize the amount of enzymes in the composition as taught by Greenberg according to teachings of Shahid et al. with a reasonable expectation of success in order to provide a composition with an improved immune strengthening properties, because Shahid et al. teach oral administration of a proteolytic enzymes formulation (bromelain, trypsin, and rutin, containing 57.9% total enzyme concentration and % 42.1 total flavonoid concentration) regulates the immune function.

Answer to Arguments

Applicant's arguments filed 12/02/2009 have been fully considered but they are not persuasive.

Applicant arguments, regarding the rejection of claim 24 under 35 U.S.C. 102(b) as being anticipated by Greenberg (Remarks, page 8), have been fully considered but they are not persuasive.

Applicant argues that Greenberg teaches the composition to be encapsulated, and that encapsulation renders Greenberg's product inappropriate as "a food product"., since Greenberg missing one of the limitations of the claim 24. However, this argument is not sound persuasive because,

According to the specification (page 23 lines 12-17)

"The composition is employed in the form of a food product as powder, sugar-coated tablet, tablet or film-coated tablet with enteric coating for a supplementary balanced diet for strengthening the immune system."

As mentioned immediately above, Greenberg discloses a dietary supplement comprising bromelain, papain, trypsin, and chymotrypsin (plant and animal proteases), vitamins (A, C and E), selenium-containing substances (selenium amino acid complex), citrus bioflavonoid complex, amino acids (L-glycine), and mucopolysaccharides (polysaccharides). Greenberg further disclose the composition has the ability to strengthen the immune system. Greenberg discloses the ingredients are granulated into powder which is then encapsulated (column 6 lines 12-14). Greenberg teaches encapsulation to preserve nutrients, and that encapsulation allows the nutrients to be released into the digestive tract after a predetermined amount of time, using a high protein vegetable as the encapsulating agent. It must be noted that, a person of ordinary skill in the art at the time the invention was made would have realized that

enzymes and nutrients encapsulated in a high protein vegetable is appropriate as a food product. Therefore, Greenberg et al. anticipate the claimed food composition.

Applicant argues (p.11 3rd paragraph of Remarks) that Greenberg teachings of the effects of enzymes on the nutrients in his vitamin and mineral formulation suggest that increasing the enzyme concentration in Greenberg's formulation would render his formulation unsatisfactory. These arguments have been considered but are not found persuasive, because Greenberg teach including enzymes in the dietary supplement aid in absorption of the vitamin and thereby optimizing the bioavailability of the nutrients (column 4 lines 45-50).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on IFP.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kade Ariani
Examiner
Art Unit 1651

/Leon B Lankford/
Primary Examiner, Art Unit 1651